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United States Department of Agriculture

Food Safety and Inspection Service

April 8, 1986 thru May 23, 1986

Compilation of Meat and Poultry Inspection Issuances

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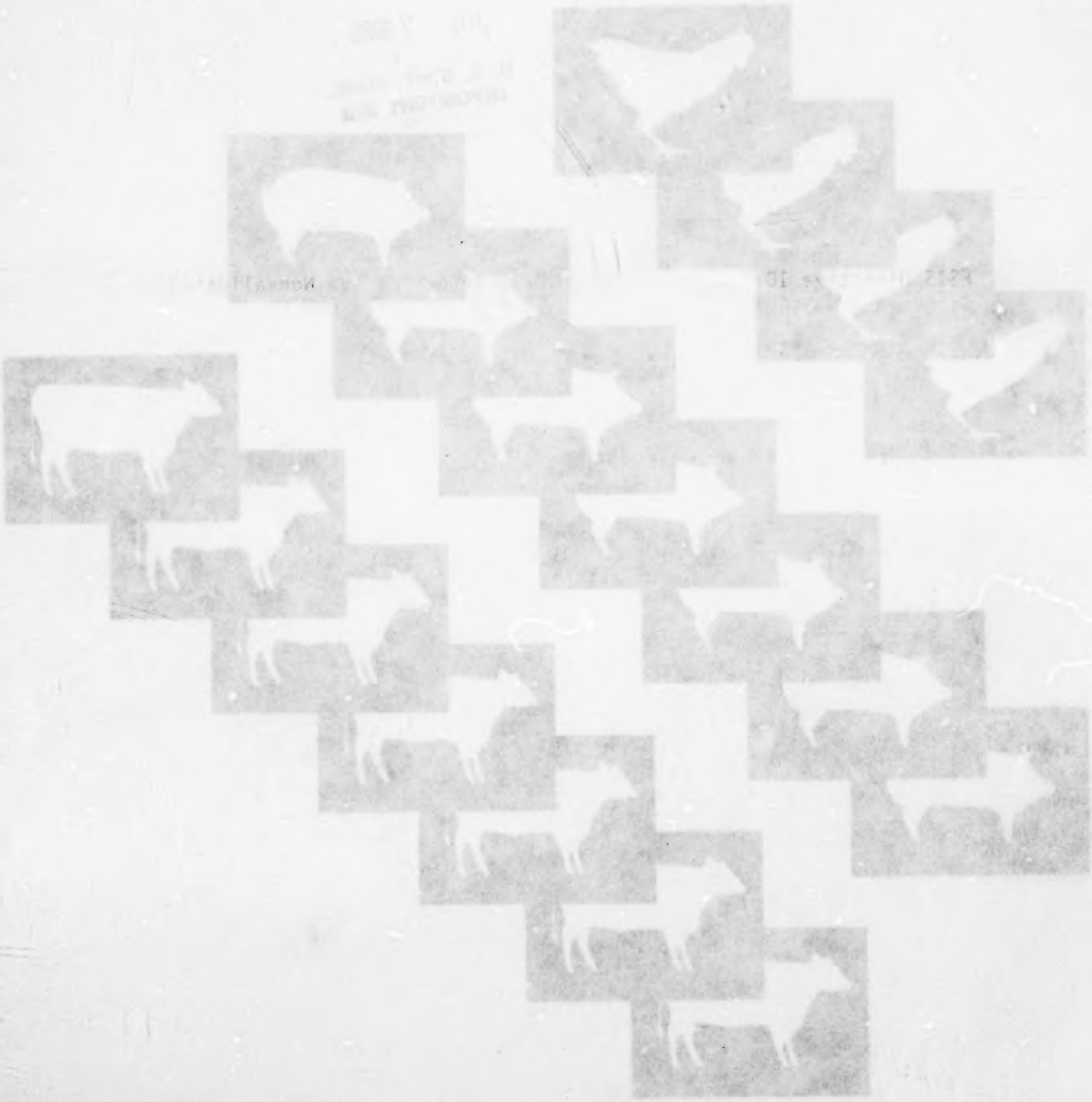

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The period covered in this Issuance is April 8, 1986, through May 23, 1986.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE
☐ REVISION
☒ AMENDMENT
☐ OTHER

FSIS Directive Destination Laboratories for Surveillance Residue Testing	10620.1 Amendment 3	4/8/86

I. PURPOSE

This document transmits a revision to FSIS Directive 10620.1.

II. CHANGES

This Amendment identifies destination laboratories for surveillance sample submission.

III. FILING INSTRUCTIONS

File this Amendment with FSIS Directive 10620.1.

IV. CANCELLATIONS

Amendment 2 to FSIS Directive 10620.1, dated 10/1/85, is cancelled.

James K. Payne (for)
Deputy Administrator
Meat and Poultry Inspection Operations

Attachment

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, TRA, ABB, R&E, Import Offices

OPI: SCI/Field Services Laboratory Division

DESTINATION LABORATORIES FOR SURVEILLANCE AND SPECIAL SAMPLES

A. Send antibiotics and Chloramphenicol samples including confirmation of positive samples from STOP to:

Region	Laboratory
1. Domestic Program	
Northeastern, Southeastern	Athens, Georgia
North Central, Southwestern	St. Louis, Missouri
Western	Alameda, California
2. Import Program (IFO = IMPORT FIELD OFFICE)	
IFO'S 1,2,3,4,5, and 6 (F Samples)	Athens, Georgia
IFO's 7 and 10 (F Samples)	St. Louis, Missouri
IFO's 8 and 9 (F samples)	Alameda, California

The Laboratory for Import Program "S" samples will be designated on a case-by-case basis with the concurrence of the Director of the Field Service Laboratories Division.

B. Send Sulfonamide samples to:

Region	Laboratory
1. Domestic Program	
All Regions	St. Louis, Missouri
2. Import Program	
IFO's 1,2,3,4,5, and 6	Athens, Georgia
IFO's 7,8,9, and 10	St. Louis, Missouri

C. Send Chlorinated Hydrocarbon, PBB, PCB Samples to:

Region	Laboratory
1. Domestic Program	
Northeastern, Southeastern	Athens, Georgia
Western, North Central and Southwestern	Alameda, California
2. Import Program	
IFO's 1,2,3,4,5, and 6	Athens, Georgia
IFO's 7,8,9, and 10	Alameda, California

D. Send Albendazole, Arsenic, Clorsulon, Decoquinate, Ivermectin, Kepone, Lasalocid, Mercury, Monensin, Morantel and Pyrantel Tartrate, Narasin, Nitrosamines, Selenium, and trace elements (heavy metals), samples to:

Region	Laboratory
1. Domestic Program	
All Regions	Athens, Georgia
2. Import Program	
All IFO's	Athens, Georgia

E. Send Amino Acids, Amoxicillin, Benzimidazoles, Carbadox, Dibutyltin Dilaurate, Diethylstilbestrol (Chemistry), Ethylene Dibromide, Gentamycin, Ipronidazole, Levamisole, Melengesterol Acetate (MGA), Narasin, Phencyclidine (PCP), Styrene, Thiabendazole, Tylosin and Zeranol samples to:

Region	Laboratory
1. Domestic Program	
All Regions	St. Louis, Missouri
2. Import Program	
All IFO's	St. Louis, Missouri

F. Send Apramycin, Halofuginone, Larvadex (R) (Cyromazine) and Pentachlorophenol (PCP) to:

Region	Laboratory
1. Domestic Program	
All Regions	Alameda, California
2. Import Program	
All IFO's	Alameda, California

G. Send Estrogenic Compound (Histopathology) samples to:

Region	Laboratory
1. Domestic Program	
Northeastern, Southeastern	Athens, Georgia
North Central	St. Louis, Missouri
Southwestern, Western	Alameda, California
2. Import Program	
IFO's 1,2,3,4,5, and 6	Athens, Georgia
IFO's 7 and 10	St. Louis, Missouri
IFO's 8 and 9	Alameda, California

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10520.1 | 5-16-86

PUMPED BACON SAMPLING PROGRAM -- NITROSAMINE ANALYSIS

I. PURPOSE

This directive prescribes procedures for pumped bacon sampling for nitrosamine analysis. This directive should be used in conjunction with the guidelines provided in the booklet titled "Bacon Sampling Program for Nitrosamine Analysis," July 1979.

II. CANCELLATIONS

This directive cancels MPI Bulletins 78-62, 78-63, 78-74, 78-85, 78-86, 78-101; and Bacon Sample Instructions to Inspectors, undated.

III. RESERVED

IV. REFERENCES

Section 318.7, Meat Inspection Regulations; Bacon Sampling Program for Nitrosamine Analysis, July 1979.

V. RESERVED

VI. POLICY

A. This directive and the prescribing regulations (9 CFR 318.7) apply only to bacon prepared from pork bellies which are pumped with curing solutions. Plants which do not manufacture pumped bacon (e.g., only slice and package bacon) are not involved in this sampling program.

B. In accordance with section 318.7 of the meat inspection regulations, FSIS conducts a sampling program to assure that pumped bacon manufactured in accordance with these regulations does not contain confirmable levels of nitrosamines when fried. The sampling program consists of three phases--monitoring, confirmation, and retention. Before a curing solution's use may be permitted, its formulation must be identified by FSIS as an "acceptable curing solution" for the preparation of pumped bacon. Pumped bacon will be prepared

DISTRIBUTION: All MPI Offices, T/A Meat Inspectors, Meat Plant Management, T/A Meat Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: Meat and Poultry Inspection Operations

in accordance with a plants acceptable process procedure(s) (See section VII, E.). Where more than one procedure is in use at the same time, continuous identification of procedure and product shall be maintained during preparation, processing, storage, and sampling. Precooking at the plant does not exempt the bacon from the requirements of the regulations. Cover pickle containing nitrate and/or nitrite is not permitted in the preparation of pumped bellies. This does not preclude the preparation of pork bellies (not pumped) by immersion curing with a cover pickle containing nitrate and/or nitrite.

VII. DEFINITIONS

A. **Monitoring phase**. A plant which has never experienced a non-compliance pumped bacon sample finding or is preparing pumped bacon using a currently approved alternate procedure -- pumped bacon moves unrestricted in commerce.

1. A sample consists of two 1-pound packages of regular sliced bacon or that equivalent of bulk sliced bacon randomly selected from a single production shift.

2. Where only slab bacon is available, a sample will consist of a 2½ pound portion from a single slab bacon.

B. **Confirmation phase**. A plant which has experienced a non-compliance finding of a monitoring phase sample -- pumped bacon usually moves unrestricted unless otherwise indicated.

1. A sample consists of six 1-pound packages of regular sliced bacon or that equivalent of bulk sliced bacon from a single current production shift.

2. Where only slab bacon is available, a sample will consist of a 2½ pound portion from each of three slabs of bacon.

3. See Section IX, B, Sample Results, for actions on laboratory findings.

C. **Retention phase**. A plant which has experienced a non-compliance finding of a confirmation phase sample -- all pumped bacon in the plant is retained. Operators of involved plants are provided the options to sample each retained production shift; divert retained bacon for use as a material in products where nitrosamine formation will not occur; or destroy all retained bacon.

When the sampling option is selected:

1. A sample of 12 pounds of bacon from each identifiable production shift shall be randomly collected in three separate parts, each consisting of four 1-pound packages of regular sliced bacon or that equivalent of bulk sliced bacon.

2. Where only slab bacon is available, a sample of 15 pounds of bacon shall be collected in three separate parts, each consisting of a 2½ pound portion from each of two slabs of bacon.

3. See Section IX, C, Sample Results for actions on laboratory findings.

D. **Acceptable curing solution.** The ingredient makeup of a pumped bacon curing solution which was determined by FSIS to satisfy the critical ingredient (i.e., nitrite, ascorbate) restrictions of section 318.7 of the meat and poultry inspection regulations.

E. **Process procedure.** A detailed write-up of information as indicated in the process chart (FSIS Form 10,520-1) outlined in the attachment shall be provided by plant operators and filed in the assigned inspectors office for:

1. Any process procedures approved by FSIS for plants that have never experienced a non-compliance result in any phase or,

2. Any currently approved alternate procedures (see Section VII, F).

NOTE: Each process procedure shall be identified distinctly in a manner acceptable to the inspector in charge and the circuit supervisor.

F. **Approved alternate process procedure.** A procedure, previously approved by FSIS (i.e., five production shift samples, each weighing 6 pounds if sliced or 7½ pounds if slab, analyzed and found to be acceptable by an FSIS accredited laboratory or the FSIS government laboratory) which a plant may elect to utilize if they experience a non-compliance finding in the monitoring or retention phase (see Sections IX, A or C). Whenever an accredited laboratory is identified to analyze samples, a duplicate number of samples will be collected and sent to the FSIS laboratory as inter laboratory check samples.

G. **Production lot.** One shifts production of pumped bacon.

VIII. SAMPLE COLLECTION/SUBMISSION PROCEDURES

A. The following are general sample collection procedures for the pumped bacon sampling program. The Residue Staff, Science Program, using a computer program identifies when inspectors will collect and submit monitoring phase samples. Confirmation and retention phase samples are coordinated by the regional offices and the Residue Staff. FSIS Form 6000-2 will be sent to inspectors for use in sample collection under the monitoring phase at the time a sample is requested. The FSIS Form 6000-1 will be used for sample collections in the confirmation, retention, and procedure change phases. Inspectors shall prepare a Form 6000-1 for each production lot of bacon samples, i.e., five forms for a process change, one form for a confirmation sample and one form for each retained production lot. Forms accompanying samples should be protected in plastic bags. Forms accompanying audit samples shall identify the name and address of the accredited laboratory doing the sample analysis.

1. During the monitoring phase, when a plant is not producing bacon on the collection date designated on the FSIS Form 6000-2, determine the next slicing date and contact program supervision for instructions.

2. The regional office will be updated through channels concerning plants that are starting or discontinuing pumped bacon operations.

3. Plant management must be informed immediately prior to collecting samples and given the opportunity to participate in companion sample collections if they desire.

4. Collect "regular" sliced bacon. DO NOT sample bacon that is labeled "thick sliced" or "thin sliced." Labeling such as "sliced bacon" or "regular sliced bacon" will be considered regular sliced bacon regardless of number of slices per pound. Where regular sliced bacon is not prepared, collect samples of slab bacon.

5. If slab bacon must be used for sampling, the selected portion(s) should have the rind removed and be sliced (approximately 10 slices per inch). If slicing is not possible, send the whole selected portion(s) to the laboratory. DO NOT cut the slab portion(s) into pieces.

6. On the bottom of the FSIS Form 6000-2, or in block 15 of FSIS Form 6000-1, list the product name and ingredients, the in-plant control number of the approved procedure the sample represents, and the production lot from which it was collected.

7. Where possible, also identify on the FSIS Forms 6000-1 or the 6000-2 if the sample bacon originated from fresh or frozen bellies.

B. Sample Submission Procedures. (Refer to FSIS Directive 10600.1 for sample shipping procedures.)

1. General

a. All samples must be completely chilled. **DO NOT freeze samples**. Plastic canisters of frozen coolant will be placed into the transtemp sample containers with the chilled bacon just prior to mailing the sample.

b. Insert sample in the shipping carton with as few folds as possible as the bacon must be separated and pan fried for testing.

c. Package sample and send "priority mail." Where sample containers are not readily available, collect sample as specified and hold under refrigeration and official security. Immediately contact the regional office, through channels, to provide sample containers.

2. Monitoring, confirmation, and inter laboratory check samples are sent to the FSIS laboratory in Athens, Georgia.

3. Retention phase samples will normally be sent to the FSIS laboratory in Athens, Georgia, but may upon request from the management of involved establishments and approval of the regional office be sent to an accredited laboratory. Whenever an accredited laboratory is used, a set of three inter laboratory check samples from each retained production shift must also be sent to the FSIS laboratory and identified as "check samples - retention phase."

IX. SAMPLE RESULTS

A. Monitoring phase. Whenever a monitoring phase sample analysis identifies a presumptive noncompliance nitrosamine level, the inspector will be notified to place the involved plant into the confirmation phase and collect a confirmation sample.

NOTE: Where the operators of a plant have an approved and tested alternate procedure (see Section VII, F) and they elect to immediately change to the alternate procedure, a confirmation sample is not required and the plant will be permitted to remain in the monitoring phase.

B. Confirmation phase.

1. Whenever confirmation sample findings indicate acceptable levels of nitrosamines, the inspector-in-charge will be notified to return the plant to the monitoring phase.

2. If confirmation sample findings indicate noncompliance levels of nitrosamines, the inspector-in-charge will be notified to place the plant into the retention phase (see Section VII, C).

C. Retention phase.

1. Whenever the results of all three parts of a retained lot sample indicate the product is in compliance, release the particular lot of product represented by that sample.

2. If the results of any part of a retained lot sample indicate noncompliance levels of nitrosamines, the insepctor-in-charge will notify plant management of the findings and inform them of available options for disposition of the particular lot (see Section VII, C).

3. The plant may return to the monitoring phase for new productions only when an approved and tested alternate procedure (see section VII, F) is made available to the assigned inspector and FSIS supervision indicates concurrence with this action.

Deputy Administrator
Meat and Poultry Inspection Operations

Attachment
FSIS Form 10,520-1

This information collection is voluntary. This information is needed in order to monitor nitrosamine levels in cured bacon. FSIS uses this information to determine whether or not a plant is in compliance.

OMB No. 0583-0015

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

PUMPED BACON SAMPLING PROGRAM–NITROSAMINE ANALYSIS PROCESS CHART

EST. NAME			EST. NO.
PROJECT NO.	COLLECTION DATE	PROCEDURE LABORATORY TESTED-ACCEPTABLE ☐ Yes ☐ No	
NAME OF USDA OR ACCREDITED LABORATORY		FRY DATES	

BACON PICKLE FORMULA FOR: ☐ Skin On ☐ Skin Off

INGREDIENTS	LBS.	OZS.
WATER		
SALT		
SUGAR (Dextrose)		
SODIUM PHOSPHATE		
SODIUM ASCORBATE		
SODIUM ERYTHORBATE		
NITRITE (Sodium)		
NITRITE (Potassium)		
TOTAL		

CURE CYCLE	PERCENT PUMP	
	DRAIN TIME	
SMOKE CYCLE	TIME IN SMOKE	
	PERCENT HUMIDITY	
	SMOKEHOUSE TEMP.	
	BACON INTERNAL TEMPERATURE	
COOLER CYCLE	TIME HELD	
	PERCENT SHRINK	

SODIUM ERYTHORBATE OR SODIUM ASCORBATE LABELLED LESS THAN 100% PURE? ☐ Yes ☐ No — IF YES, WHAT IS %?

SUBMITTED FOR APPROVAL BY (Plant Official Signature) — DATE SIGNED

MONITORING SAMPLES SUBMITTED BY	DATE	PASSED	PRESUMPTIVE	SAMPLE NUMBER

DATE THE PROCEDURE WAS:

PLACED IN USE	DISCONTINUED	PLACED ON SHELF

CONFIRMATION SAMPLES SUBMITTED ☐ Passed ☐ Failed

REMARKS

REGIONAL OFFICE USE ONLY

FSIS FORM 10,520-1 (1/86)

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

10.110.1 | 5-14-86

DATA REPORTING FOR NONVALIDATED CHEMICAL METHODS (NVCM)

I. PURPOSE

This Directive prescribes policy concerning the reporting of analytical values for compounds where the analytical method (or methods) has not met Agency requirements for validation or collaboration by a multilaboratory study or has not been submitted for study. This Directive also identifies analyst and supervisory responsibilities in reporting data when using NVCM's.

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

Method E691, paragraph 16.8.3; American Society for Testing Materials

Dixon's Rules, Processing Data for Outliers; Biometics 9, 7 (1953)

V. ABBREVIATIONS

The following will appear in their shortened form in this Directive:

CD	Chemistry Division
CV	Coefficient of Variation
EP	Emergency Programs
FIAD	Food Ingredient Assessment Division
FSLD	Field Service Laboratories Division
MPL	Minimum Proficiency Level
NVCM	Nonvalidated Chemical Method
PPB	Parts Per Billion
PPM	Parts Per Million
REPD	Residue Evaluation and Planning Division
SCI	Science Program
SRV	Sensitivity Rounding Value for the Analyte
X	Analyte Concentration of Interest

DISTRIBUTION: All MPI Offices (Except Circuit Supervisors and below), T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: SCI - Planning, Review, and Evaluation Branch

VI. POLICY

This Directive identifies FSIS's system for reporting analytical values for compounds where the method (or methods) has not been fully or sucessfully validated or where a multilaboratory study is not warranted. However, SCI, REPD, FIAD, or EP, may require the use of NVCM's for emergency contamination responses in order to conduct exploratory surveillances, and to compile data bases in areas of interest.

VII. DEFINITION

Nonvalidated Chemical Method. An analytical procedure which (1) has not been validated in a multi-laboratory study by at least three independent analysts with a minimum of two laboratories, or (2) was subjected to a multi-laboratory study at an analyte concentration above the residue limit or (3) the determined MPL is higher than the established residue limit.

This definition does not apply to validated or collaborated analytical chemical methods extended to other species-kind and tissues by study or to analytical methods primarily used as screens to detect the presence of an analyte. However, procedures for extending analytical methods to other species-kind and tissues for use in only one laboratory are the same as described in this Directive.

VIII. REQUIREMENTS

A. New NVCM'S. To establish an analytical chemical method not already listed in this Directive as a NVCM, the following criteria will be applied to determine linearity and repeatability using fortified tissues.

1. To determine linearity, use external analyte standards at 4 nominal concentrations, 0 X, 1/2 X, X and 2 X, on three separate days. A minimum linear correlation coefficient value (r) of 0.9995 is required.

2. A minimum of 20 data points are required based on 5 replicates per set of 4 concentration levels. Fortification concentrations are at 0 X, 1/2 X, X and 2 X in the species-kind and tissue of interest. The recoveries and CV for repeatability for fortified tissues are to meet the CD guidelines for acceptability issued November 2, 1983, summarized as follows:

Analyte Concentration	CV Repeatability	Recovery
0.1 to 10 PPM	≤ 15%	80-110%
1 to 100 PPB	≤ 20%	60-115%
< 1 PPB	≤ 35%	40-120%

3. The above referenced 20 data points must be composed of at least two sets of samples prepared on different days. Replicate set analyses within day is acceptable if analysis time permits.

B. **Multiple Species-Kind/Tissues.** Analytical data for the additional species-kind or tissues requires a minimum of 12 additional data points, i.e., the four nominal concentrations in triplicate, either within day or between days. If X changes for different species-kind or between tissues, this provision does not apply.

C. **NVCM'S in Use.**

1. The NVCM'S and respective applicable species-kinds/tissues are listed in Attachment 1.

2. Additional analytical methods given the status of NVCM will be initially appended in protocols, studies, or other instruments. The intent, scope and use of the NVCM will be stated, to be followed by an amendment to this Directive which adds the new NVCM to the listing at Attachment 1.

3. Current NVCM's which have subsequently met the criteria for a validated or collaborated analytical method will be deleted by amendment to Attachment 1.

IX. ACCEPTABILITY/RESPONSIBILITIES

A. **Evaluation of Analytical Data Acceptability for Reporting**

1. The analyst(s) are to perform the assays on species-kind/tissues designated by CD, with duplicate analyses for all positives. The difference (D) in the two values to the nearest SRV should be equal to or less than the product determined by the following equation:

$$D \leq \overline{X} \bullet \frac{CV}{100} \bullet 2.0 \bullet n^{1/2}$$

Where: CV for each method is prescribed in Attachment 1.

$\overline{X}$ is the sample mean,

2.0 represents the 95% confidence interval based on ASTM Reference, and

n is the number of determinations.

If this criterion is not met, the analysis is to be repeated twice, subjecting the repeat values to the equation in IX A. 1.

2. If the criterion for data acceptability for the first or second set of duplicate values is not met in Section IX A. 1., repeat the analysis again in duplicate, and calculate the CV using all six values. The CV must be equal to or less than the CV listed at Attachment 1. If the criterion still

remains unsatisfied, repeat the analyses, add two additional values and then test the data for outliers at the 1 percent level using Dixon's rules. For reporting analytical values using this section, the CV must be based on a minimum of six values in order to report a mean as well as meet the criteria for the 95 percent confidence interval in IX A. 1.

B. **Reporting of Data.**

1. The SRV is the least significant numerical unit in the measurement used for calculating a result in an analytical determination. For the case described in IX A. 1., the analyst reports the mean of the two acceptable values rounding the analytical value to one significant figure less than the SRV. Example: If the SRV is 0.01 ppm, then the mean is reported to the nearest 0.1 ppm. For analytical values ten times greater than the initial analytical data base for evaluation, increase the SRV by a factor of ten, and report the mean to one significant figure less than the revised SRV. For analytical values which are additional orders of magnitude, e.g., 100 or 1000 times above the initial data base, the same format is followed.

2. For the case described in IX A. 2., the analyst reports the mean of all analyses performed, rounding the analytical value to one significant figure less than the SRV.

D. **Supervisory Review.**

1. The responsible FSLD supervisor shall review all instrument recordings, laboratory notebooks, analytical calculations, statistical data, and any other pertinent documents prior to reporting data on FSIS analysis forms.

2. The CD Staff reviews all data generated in establishing an analytical method as a NVCM.

Ronald E. Engel

Ronald E. Engel, Deputy Administrator
Science Program

Attachment

Table of Nonvalidated Chemical Methods

TABLE OF NONVALIDATED CHEMICAL METHODS

Method	Reference	Repeatability Expected CV(%)	SRV	Species-Kind; Tissues
Arsenic-Atomic Absorption	CD Guidebook 5.009	15	0.01 PPM	All; Liver, Kidney, and Muscle
[1]Chlorinated Triazines	CD Guidebook 5.032	15	0.1 PPB	All; Fat
[2]Decoquinate	CD Guidebook 5.030	20	0.01 PPM	Bovine; Muscle only
Dibutyltindilaurate	FDA TA-22, TA-31	10	0.01 PPM	Turkey; Liver . and Muscle
[1]Morantel/Pyrantel Tartrate	Pfizer - New Animal Drug Application Methods; J.AOAC-65(2), 227 (1982)	20	0.01 PPM	Bovine and Swine; Muscle only
Polybrominated Biphenyls	Hazelton-Raltech State of Michigan	15	0.1 PPB	All; Fat
Tetracyclines/HPLC	CD Guidebook 5.031	35	0.01 PPM	All; Liver, Muscle, and Kidney
Tylosin	ARS Moats Method	20	0.01 PPM	Bovine; Muscle
[1]Diethylstilbestrol	HFB Derivative (CD Method)	30	0.01 PPB	Bovine and Sheep; Kidney, Liver and Muscle
Kepone	J. AOAC, Vol. 61, No. 1, 8-14 (1978)	10 and 20	0.01 PPM	All; Fat and Liver

TABLE OF NONVALIDATED CHEMICAL METHODS

Method	Reference	Repeatability Expected CV(%)	SRV	Species-Kind; Tissues
[1]Levamisole	CD Guidebook 5.033	15	0.001 PPM	All Red Meat; Liver & Muscle
Organophosphates	CD Guidebook 5.006	20	0.001 PPM	All Red Meat;
- Dichlorvos				Liver and Muscle
- Ruelene				Liver and Muscle
- Guthion				Liver and Muscle
- Coumaphos oxygen analog				Liver and Muscle
[1]Hydroxyipronidazole	CD Guidebook 5.013	25	0.01 PPB	Turkey and Swine; Muscle
Benzimidazoles	Hazelton Raltech Inc. No. 6128-100 3/20/85	15	0.001 PPM	Red Meat;
-Thiabendazole & Hydroxythiabendazole				Liver and Muscle
-Fenbendazole				Liver and Muscle
-Oxfendazole				Liver and Muscle
-Mebendazole				Liver and Muscle
Clopidol	JAOAC Vol. 67, No. 2 334-336 (1984)	10	0.01 PPM	Poultry; Liver
[1,3] Alumina Column (chlorinated hydrocarbon pesticides)	CD Guidebook 5.002	20	0.001 PPM	All; Fat
- Hexachlorobenzene (HCB)				
- Benzenehexachloride (BHC)				
- Dieldrin				
- p,p DDE				
- p,p DDD				
- p,p DDT				
- Endrin				

TABLE OF NONVALIDATED CHEMICAL METHODS

Method	Reference	Repeatability Expected CV(%)	SRV	Species-Kind; Tissues
"Alumina Column" (continued)				
- Heptachlor and Epoxide				
- Lindane				
- Mirex				
- Cis and Trans chlordane				
- Polychlorinated biphenyl (PCB)-1260				
- Aldrin				
- Oxychlordane				

1 Requires mass spectral confirmation to report positive analytical findings.

2 Requires gas chromatography analysis to report positive analytical values.

3 Used only for reporting results for imported products when insufficient adipose tissue is available for the Mills procedure.

Amendments will be periodically issued by CD when the status of a NVCM has changed.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

9225.3 | 5-23-86

EXPORT OF FULLY CURED BACON, HAM, AND PORK SPARE RIBS TO THE UNITED KINGDOM

I. PURPOSE

This directive provides information about supplementary certification statements required for the export of fully cured bacon, ham, and pork spare ribs to the United Kingdom from the United States.

II. CANCELLATION

FSIS Notice 20-85.

III. (RESERVED)

IV. REFERENCES

A. MPI Manual, Section 22.39.

B. Current plant list published as an FSIS Notice: "Meat Plants Eligible to Export Further Processed Meat Products to the United Kingdom."

V. FORMS

The following will appear as abbreviated in this directive:

MP Form 130	Meat and Poultry Certificate of Wholesomeness (5/80 or newer).
MP Form 158	Health Certificate for Meat Products Intended for Consignment to the United Kingdom (4/85 or newer.)

VI. GENERAL REQUIREMENTS

A. **Product involved.** Fully cured unsliced (slab) bacon, sliced bacon, ham, and pork spare ribs.

B. **Eligible plants.** Refer to the current FSIS Notice, "Meat Plants Eligible to Export Further Processed Meat Products to the United Kingdom," which specifies plants currently certified as eligible to export to the United Kingdom.

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, TRA, ABB

OPI: IP/ECD

C. **Certification.** All certificates and supplementary statements must be signed by an FSIS veterinarian. Issue the following forms:

1. MP Form 130. See Attachment 1.

2. MP Form 158. See Attachment 2.

3. USDA/FSIS Letterhead Certificate (see Attachment 3) with the following statements:

a. For all product: "The products are derived from:

(1). Animals which have remained in the territory of the United States of America and Canada for at least 3 months before being slaughtered or since birth in the case of animals less than 3 months old.

(2). Animals which have not come from holdings which for health reasons are subject to prohibition as a result of an outbreak of porcine brucellosis during the previous 6 weeks.

(3). Animals which have been subjected to ante- and post-mortem inspection by a veterinary officer approved by the Government of the United States of America and found to be healthy."

b. And for sliced bacon:

"The bacon has been pumped with brine under a pressure of 50 lbs. or more to the square inch and subsequently smoked for a period of not less than 12 hours at a temperature of not less than 120°F."

c. And for ham, unsliced bacon and spare ribs, as applicable:

(1). "The product has been subjected to pumping with brine under a pressure of 80 lbs. or more to the square inch and subsequently soaked in brine or dry salting for a period of not less than 4 days."

(2). The product has been subjected to salting (wet salting or dry salting) for a period of not less than 10 days.

This information must be used in conjunction with the requirements specified in Section 22.39 of the MPI Manual and other notifications pertaining to the United Kingdom.

Deputy Administrator
Meat and Poultry Inspection Operations

Attachments
1. MP Form 130
2. MP Form 158
3. USDA/FSIS Letterhead Certificate

ATTACHMENT 1

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION OPERATIONS

MEAT AND POULTRY EXPORT CERTIFICATE OF WHOLESOMENESS

A knowingly false entry or false alteration of any entry on this certificate may result in a fine of not more than $10,000 or imprisonment for not more than five years or both (18 USC 1001). Additional penalties exist under the Federal Meat Inspection Act [21 USC 611 (c) (1), (2), and (5), 21 USC 678] and the Poultry Products Inspection Act [21 USC 458 (c) (1), (2), and (5), 21 USC 461] for an unauthorized or false alteration or misuse of this certificate.

AREA OFFICE	COUNTRY OF DESTINATION	DATE ISSUED	
Madison, WI	United Kingdom	March 13, 1986	MPA- 811005

EXPORTED BY *(Applicant's name and address including ZIP Code)*

Sevier Food Products Corp.
1700 James Avenue
Madison, WI 53707

CONSIGNED TO *(Name and address, including ZIP Code)*

HRI Provision Co.
4200 Manchester Rd.
London, England (ZIP)

PRODUCT EXPORTED FROM:

EST/PLANT NUMBER *(If applicable)*: Est. 428X

CITY: Madison, Wisconsin

- [X] @ SLAUGHTERING PLANT
- [X] @ PROCESSING PLANT
- [ ] @ WAREHOUSE
- [ ] @ DOCKSIDE

TOTAL MARKED NET WEIGHT	TOTAL CONTAINERS
504 lb.	21 ctns

PRODUCT AS LABELED	MARKED WEIGHT OF LOT 1/	NUMBER OF PACKAGES IN LOT 1/	SHIPPING MARKS 1/	EST/PLANT NUMBER ON PRODUCT
Sliced bacon 24 x 1 lb.	24 lb.	21 ctns	USLU/6804	Est. 428X

1/As stated by applicant or contractor

SPECIMEN

REMARKS

See supplementary certification sheet attached.

[X] **I CERTIFY that the meat or meat food product specified hereon is from animals that received both antemortem and postmortem inspection and were found sound and healthy and that it has been inspected and passed as provided by law and regulations of the Department and is sound and wholesome.**

[ ] **I CERTIFY that the poultry and poultry products specified above came from birds that were officially given an antemortem and postmortem inspection and passed in accordance with applicable laws and regulations of the United States Department of Agriculture and are wholesome and fit for human consumption.**

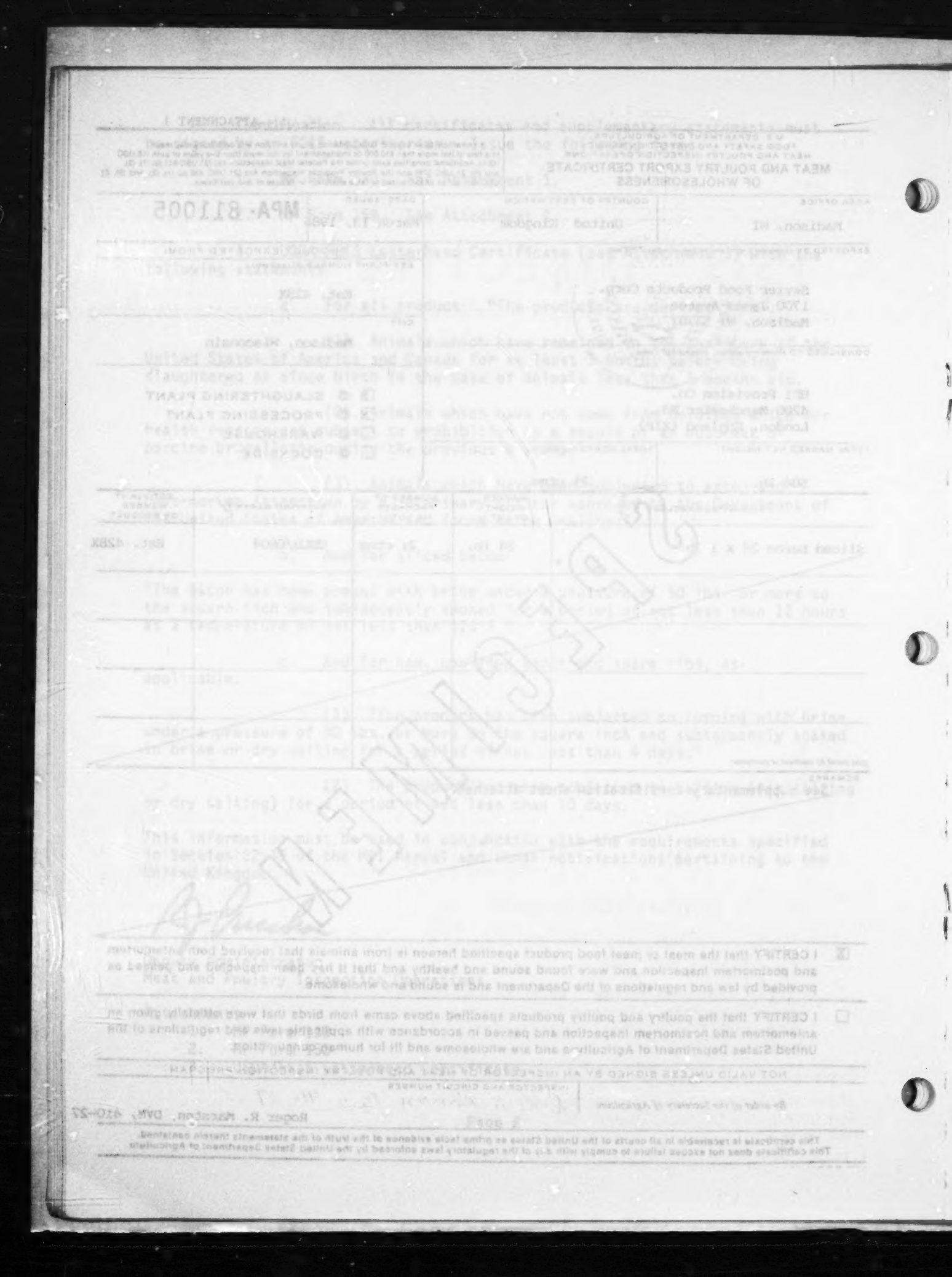
NOT VALID UNLESS SIGNED BY AN INSPECTOR OF MEAT AND POULTRY INSPECTION PROGRAM

By order of the Secretary of Agriculture

INSPECTOR AND CIRCUIT NUMBER

Roger R. Marston, DVM, 410-27

This certificate is receivable in all courts of the United States as prima facie evidence of the truth of the statements therein contained. This certificate does not excuse failure to comply with any of the regulatory laws enforced by the United States Department of Agriculture.



ATTACHMENT 2

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
MEAT AND POULTRY INSPECTION PROGRAM

HEALTH CERTIFICATE FOR MEAT PRODUCTS INTENDED FOR CONSIGNMENT TO THE UNITED KINGDOM

SERIAL NO. OF CORRESPONDING EXPORT CERTIFICATE: MPA 811005

EXPORTING COUNTRY: UNITED STATES OF AMERICA

MINISTRY: U.S. DEPARTMENT OF AGRICULTURE

DEPARTMENT CONCERNED: FOOD SAFETY AND INSPECTION SERVICE

I. IDENTIFICATION OF MEAT PRODUCTS

PRODUCTS MANUFACTURED WITH MEAT FROM (Animal Species)		NATURE OF PRODUCTS (1)	
Swine		Sliced bacon	
NATURE OF PACKAGING	**NUMBER OF PACKAGES**	**STORAGE AND TRANSPORT TEMPERATURE (2)**	**NET WEIGHT**
24 x 1 lb. pkge.	21 ctns.	40 °F	504 lbs.

II. ORIGIN OF MEAT

ADDRESS(es) AND VETERINARY APPROVAL NUMBER(s) OF APPROVED PROCESSING ESTABLISHMENT(s)

Sevier Food Products Corp. Est. 428X
1700 James Avenue
Madison, WI 53707

III. DESTINATION OF MEAT

THE MEAT PRODUCTS WILL BE SENT FROM (Place of Loading)	MEANS OF TRANSPORT (3)
Madison, WI	(Ship) John L. Cooke
NAME AND ADDRESS OF CONSIGNOR	**NAME AND ADDRESS OF CONSIGNEE**
Sevier Foods Products Corp. 1700 James Avenue Madison, WI 53707	HRI Provision Co. 4200 Manchester Rd. London, England (ZIP)

IV. HEALTH ATTESTATION

I, the undersigned, certify that:

(a) the meat products described above were manufactured from fresh meat or meat products under conditions that comply with the standards laid down in the Explanatory Memorandum on the Importation of Meat Products into the United Kingdom;
(b) the said meat products, their wrappings or packaging, bear a mark proving that they have all come from approved establishments;
(c) the fresh pigmeat used in the manufacture of the meat products was/has not been (4) subject to a trichinae detection test;
(d) the transport vehicles and equipment and the loading conditions of this consignment comply with the hygiene requirements laid down in the Explanatory Memorandum on the Importation of Meat Products into the United Kingdom.

SUPERSEDED

(1) Possible indication of ionizing radiation for medical reasons.
(2) Where an indication is given in accordance with Part II Section E, paragraph 23 of the Explanatory Memorandum on the Importation of Meat Products into the United Kingdom. (For other than shelf stable products, the maximum temperature at which the product may be transported or stored must be specified.)
(3) Indicate the registration number (railway wagons and trucks); the flight number (aircraft) or the name (ship).
(4) Delete as appropriate.

DONE AT: Madison, WI
ON (Date): March 13, 1986
SIGNATURE: Roger R. Marston DVM 410-27
PLEASE PRINT NAME IN CAPITAL LETTERS: Roger R. Marston, DVM, 410-27

MP FORM 158 (4/85)

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

ATTACHMENT 3

March 13, 1986

Supplementary Certifications For Corresponding Export Certificate No. MPA 811005.

I, a veterinary officer duly designated by the United States Government, certify that:

A. The products are derived from:

1. Animals which have remained in the territory of the United States of America and Canada for at least three months before being slaughtered or since birth in the case of animals less than three months old.

2. Animals which have not come from holdings which for health reasons are subject to prohibition as a result of an outbreak of porcine brucellosis during the previous six weeks.

3. Animals which have been subjected to ante- and post-mortem inspection by a veterinary officer approved by the Government of the United States of America and found to be healthy.

B. Sliced bacon statement:

"The bacon has been pumped with brine under a pressure of 50 lbs. or more to the square inch and subsequently smoked for a period of not less than 12 hours at a temperature of not less than 120 °F."

SPECIMEN

Roger R. Marston, DVM, 410-27

PREVIEW

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

[X] DIRECTIVE
[ ] REVISION
[X] AMENDMENT
[ ] OTHER

FSIS DIRECTIVE	7220.1	
STANDARDS AND LABELING DIVISION POLICY MEMORANDA	Amend. 17	5-20-86

I. PURPOSE

This document transmits changes to FSIS Directive 7220.1.

II. CHANGES

Insert Policy Memo 096 in numerical order in attachment 1 of FSIS Directive 7220.1.

III. CANCELLATIONS

This change transmittal is cancelled when contents have been incorporated.

Margaret O'K. Glavin

Director
Standards and Labeling Division
Meat and Poultry Inspection Technical Services

Attachment

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, ABB

OPI: MPITS - Standards and Labeling Division

United States Department of Agriculture

Food Safety and Inspection Service

MAY 7 1986

To Branch Chiefs, SLD

Policy Memo 096

From: Margaret O'K. Glavin, Director
Standards and Labeling Division, MPITS

Margaret O'K. Glavin

Subject: Approval of Labels for Experimental/Sample Products

ISSUE: Are there conditions under which an Inspector-in-Charge (IIC) of an official establishment may approve labels for experimental/sample (E/S) products?

POLICY: IIC's may approve labels for E/S products which are prepared in official establishments and distributed to one or more locations for the purpose of consumer sampling and/or pre-market evaluation. Specific requirements for IIC approval of E/S product labels are as follows:

1. Each request for approval must be made using a USDA application for label approval form (FSIS Form No. 8822-1). The application must include the complete formula and a detailed manufacturing procedure.

2. All ingredients must be approved for use in the meat and poultry inspection regulations. Use of such ingredients must conform to the conditions and restrictions listed in the regulations.

3. Labels must bear all mandatory labeling features required by the meat and poultry inspection regulations.

4. The phrase "Not For Sale" must be prominently displayed on the label.

5. A statement of intended distribution must be included on the label, e.g., "For Test Purposes Only", "Experimental Product", "Consumer Samples."

6. Products labeled with a standardized name must conform to the standard.

7. The quantity of E/S product distributed under a single IIC label approval may not exceed 500 pounds and may not extend beyond 60 days from the date of the approval.

Circuit supervisors (CS) may grant one consecutive extension of up to an additional 500 pounds and/or 60 days.

8. The IIC must retain copies of all approved E/S product labels and application forms for two years from the approval date.

8a. The IIC should examine the file indicated in 8 to assure that the same E/S product had not been produced before, or at least not produced during the past 2 years.

9. Plant management must maintain production and distribution records of E/S products for at least 2 years, and make such records available to the IIC upon request.

10. E/S product labels containing information or statements significantly beyond the mandatory information, e.g., negative, natural or nutritional claims, must receive prior approval from the Standards and Labeling Division (SLD) in Washington, D.C.

If a plant applies to SLD for E/S approval it should indicate if previous approvals had been granted by the IIC. All extensions beyond that granted by the CS must be sent to SLD. IIC approval of E/S product labels does not in any way imply that a final approval of the label or product formulation will be granted for distribution in commerce.

RATIONALE: IIC approval of E/S product labels under the limitations described in this policy memo will permit processors to develop new products and test customer acceptance with a minimum expenditure of time and expense. During the past year SLD has authorized implementation of similar procedures on a case-by-case basis. This experience and subsequent feedback received from the Meat and Poultry Inspection Operations staff ensures that under the conditions enumerated in this policy memo, the IIC will continue to assure that only safe and wholesome E/S product, in full compliance with regulatory requirements, will be produced and distributed in limited quantities and for a limited time.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

☒ DIRECTIVE
☐ REVISION
☒ AMENDMENT
☐ OTHER

FSIS DIRECTIVE	7220.1	
Standards and Labeling Division Policy Memoranda	Amend. 16	5-2-86

I. PURPOSE

This document transmits changes to FSIS Directive 7220.1.

II. CHANGES

Insert Policy Memos 070A and 071A in numerical order in attachment 1 of FSIS Directive 7220.1.

III. CANCELLATIONS

A. Policy Memos 070 and 071 are cancelled.

B. This change transmittal is cancelled when contents have been incorporated.

Margaret O'K. Glavin

Director
Standards and Labeling Division
Meat and Poultry Inspection Technical Services

2 Attachments

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, ABB

OPI: MPITS - Standards and Labeling Division

United States Department of Agriculture

Food Safety and Inspection Service

MAR 31 1986

To: Branch Chiefs, SLD

Policy Memo 070A

From: Margaret O'K. Glavin, Director
Standards and Labeling Division, MPITS

Margaret O'K. Glavin

Subject: Fat and Lean Claims

ISSUE: What are the guidelines for the review and approval of labeling claims relating to the fat and lean content of meat and poultry products?

POLICY: This policy memo replaces Policy Memo 070. Emphatic expressions of the lean content of a meat or poultry product i.e., "lean," "extra lean," and "low fat" and comparative expressions of lean or fat content, e.g., "leaner," "lower fat," "less fat," may be used in the labeling of meat and poultry products.

"Lean" and "low fat" may be used only for those products that contain no more than 10 percent fat. "Extra lean" may be used only for those products that contain no more that 5 percent fat. In each case, the actual amount of fat in the product must be disclosed, e.g., "contains 4 percent fat" and either accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel, on the information panel or be included as a part of other nutrition information.

Comparative expressions of the lean or fat content of products may be used only if there is at least a 25 percent reduction or difference in fat or lean content from (1) the amount of fat permitted by an applicable standard if the amount of fat identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amount of fat in a market-basket survey of comparable products, or (3) the amount of fat in a similar product or class of products as found in recent applicable references such as the revised editions of Composition of

Foods - Agriculture Handbook No. 8. An explanation that includes quantitative information about the fat or lean content of the lower fat product and a comparison of its fat or lean content to any of the above references must also be included on the labeling. For example, the explanation for a product labeled "Leaner Ground Beef" might be "This product contains 20 percent fat, which is 33 percent less fat than allowed by the USDA standard for ground beef."

Fanciful names, brand names, and trademarks often include lean terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Lean Cuisine." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of lean or fat content described herein is required unless the products meet the definitions for "lean," "extra lean," or "low fat."

All products with claims about the lean content will be closely examined to assure that the products became leaner due to the replacement of fat by lean material, i.e., indigenous meat or poultry protein and the natural moisture associated with the protein. In situations where a fat content declaration would not accurately reflect the lean content of the product, a statement that discloses the actual amount of lean material in the leaner product expressed as the percent lean material or percent protein may be needed, e.g., "50 percent leaner than average _____ -- contains 25 percent protein." These statements may accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel or on the information panel.

Generally, the emphatic claims "lean" and "extra lean" will be limited to products composed solely of fat and lean material with no added substances such as water or extenders. In those limited situations where it can be demonstrated that the product before and after the addition of any added substances contained no more than 10 percent or 5 percent fat, as the case may be, the emphatic claims may be used. For example, a ham and water product could not be labeled "lean" if it contained 10 percent fat since the product became lean by dilution with water and other added substances. However, if the meat portion contained no more than 10 percent fat before processing, the product could be labeled "lean."

At the time of label approval, the fat or lean claims must be substantiated by laboratory analyses. At a minimum, three laboratory analyses are needed and, in accordance with Policy

Memo 086 on Nutrition Labeling, it is preferred that each analysis be performed on a sample from a composite of 12 packages from 12 consecutive production lots to attain an adequate representation of the fat or lean content of the product. If the explanatory statement refers to market-basket data, sufficient data must also be submitted to demonstrate that the fat or lean content is representative of products in the marketplace. If comparisons to market-basket data are made, it will be necessary that at least yearly the data are reconfirmed. A partial quality control program or nutrition labeling verification program must also be approved before the label may be used.

The policy of allowing on the labeling of whole cuts or parts of meat or poultry terms such as "lean" and "extra lean" if stated in the possessive and accompanied by a guarantee statement is withdrawn. These products must meet the definitions for use of these terms. Comparative terms, e.g., "leaner," "lower fat," etc., may be used if there is at least a 25 percent decrease in fat or increase in lean content of the product. In this case, a comparative explanation as described above is required.

Labeling not in compliance with the provisions of this policy memo should be modified as soon as possible, but no later than 1 year from the date of this memo.

RATIONALE: Labeling claims concerning a product's fat or lean content can be informative and useful to consumers in making food choices. Processors producing products with reduced amounts of fat or using leaner meat or poultry ingredients should be able to label their products to indicate this characteristic. A claim alone without some explanation of its meaning may be misleading and in most cases does not provide the information necessary to make a value judgment. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases, a disclosure of only the fat or lean content will provide the necessary information.

The policy allowing only a reduction to 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat is being withdrawn. It is recognized that this was an anomaly and it is preferable to be consistent with other policies both within this agency and the Food and Drug Administration that require a 25 percent reduction in some component before a claim can be made.

Definitions are being established for "lean," "extra lean," and "low fat" since they are absolute terms which have taken on increasing importance to the consumer in recent years. "Lean" and "low fat" are comparable in meaning and are given the same definition. "Extra lean" is given a more strict definition because consumers would expect a product so labeled to have less fat that a product labeled "lean" or "low fat."

The longstanding policy of allowing the use of fat and lean claims if stated in the possessive and accompanied by a guarantee statement is being withdrawn. The widespread interest in fat and its relation to diet demands that quantitative information be available to the consumer. Furthermore, the policy had only limited application, and it is important to have a consistent approach for all products in order to avoid confusion and promote consumer understanding.

The comparisons to leading brands, a leading brand, or the company's regular product are no longer being permitted in the interest of eliminating comparisions that have limited value. In some cases the leading brand or regular product was not marketed in the same areas as the "leaner" or "lower fat" product and these comparisons were of limted value to consumers. Also, the leading brand or regular product comparisons provide information which often is not representative of most products in the marketplace.

United States Department of Agriculture

Food Safety and Inspection Service

MAR 31 1986

To: Branch Chiefs, SLD

Policy Memo 071A

From: Margaret O'K. Glavin, Director
Standards and Labeling Division, MPITS

Margaret O'K. Glavin

Subject: Lite and Similar Terms

ISSUE: What are the guidelines for the review and approval of labeling terms such as "Lite," "Light," "Lightly" and similar terms?

POLICY: This policy memo replaces policy memo 071. Terms such as "Lite," "Light," "Lightly," may be used on the labels of meat and poultry products. Such terms generally imply that a product has significantly fewer calories than expected in a similar product, but often are used to relate that a product has significantly less fat, salt, sodium, breading and/or other components than a similar product. A significant reduction is considered to be at least 25 percent. In the case of a salt reduction, the sodium content must also be reduced by at least 25 percent (see Policy Memo 049C).

If used, the terms generally must be explained either adjacent to the term or referenced by means of an asterisk and placed elsewhere on the principal display panel or on the information panel. The explanation must provide to the purchaser quantitative information about the amount of calories, fat, salt, sodium, and/or other components in the product and include a quantitative comparison to (1) the amounts permitted by an applicable standard if the amount identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the fat content of the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amounts found in a market-basket survey of comparable products, or (3) the amounts in a similar product or class of products as found in recent applicable reference sources such as the revised editions (since 1976) of Composition of Foods -- Agriculture Handbook No. 8.

For products that are unquestionably low in calories, fat, salt, breading or sodium, the explanation required to accompany such terms need only consist of a disclosure of the actual amount in the product. For this purpose, the amount of calories can be no more than 40 calories per serving and no more than 0.4 calories per gram of product. For fat and breading, the product can contain no more than 10 percent. For salt and sodium, the product can contain no more than 35 mg of sodium per 100 grams of product.

Fanciful names, brand names, and trademarks often include lite terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Dining Lite." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of fat content described above is required. Those products containing no more than 10 percent fat may provide a declaration of fat content as the explanatory statement.

At the time of label approval, the amounts of the components in the product are to be substantiated by laboratory analyses (breading would be determined by the formulation). At a minimum, three laboratory analyses are to be performed and ideally each analysis should be from a composite of 12 ready-to-sell product units from 12 consecutive production lots. If the explanatory statement refers to market-basket data, sufficient data must be submitted to demonstrate that the data are representative of the market, and these data must be reconfirmed at least yearly. A partial quality control or nutrition labeling verification program must be approved before labeling may be used.

Labeling not in compliance with the provisions of this policy memo should be modified as soon as possible, but no later than 1 year from the date of this memo.

RATIONALE: Labeling claims that include terms such as "Lite," "Light," "Lightly," and similar terms which imply that a product has reduced levels of various components can be informative and useful to consumers in making food choices. Processors making products with reduced amounts of various components should be able to indicate this characteristic on labeling. A claim alone without some explanation of its meaning may be misleading and

certainly does not provide the information necessary for consumers to make informed judgements. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases where a product is unquestionably low in various components, a disclosure of only the absolute amount will provide the necessary information.

The policy of allowing a reduction to only 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat is being withdrawn. It is recognized that this was an anomaly and it is preferable to be consistent with other policies both within this Agency and the Food and Drug Administration that require a 25 percent reduction in some component before a claim may be made.

The comparisons to leading brands, a leading brand, or the company's regular product are no longer being permitted in the interest of eliminating comparisons that have limited value. In some cases the leading brand or regular product was not marketed in the same areas as the "lite" product and these comparisons were of limited value to consumers. Also, comparisons to the leading brand or regular product provide information which often is not representative of most products in the marketplace.

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

[X] DIRECTIVE
[ ] REVISION
[X] AMENDMENT
[ ] OTHER

FSIS DIRECTIVE STANDARDS AND LABELING DIVISION POLICY MEMORANDA	7220.1 Amend. 14	5-5-86

I. PURPOSE

This document transmits changes to FSIS Directive 7220.1.

II. CHANGES

Insert Policy Memos 66A and 95 in numerical order in Attachment 1 of FSIS Directive 7220.1.

III. CANCELLATIONS

A. Policy Memo 066 is cancelled.
B. This change transmittal is cancelled when contents have been incorporated.

Margaret O'K. Glavin

Director
Standards and Labeling Division
Meat and Poultry Inspection Technical Services

2 Attachments

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, R&E, ABB

OPI: MPITS, Standards and Labeling Division

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

CHANGE TRANSMITTAL SHEET

☒ Directive

☐ Revision

☐ Attachment

☐ Notice

FSIS DIRECTIVE
STANDARDS AND LABELING DIVISION
POLICY MEMORANDA

7220.1
Amend. 1A

3-3-86

I. PURPOSE

This document transmits changes to FSIS Directive 7220.1.

II. CHANGES

Generic Policy Memos 068 and 80 is updated every to attachment 1 of FSIS Directive 7220.1.

III. CANCELLATIONS

A. Policy Memo 068 is cancelled.
B. This change transmittal is canceled when contents have been incorporated.

Director
Standards and Labeling Division
Meat and Poultry Inspection Technical Service

2 Attachments

DISTRIBUTION: All MPI Offices, T/A Inspectors, Plant Management, T/A Plant Management, Science and Compliance Offices, Import Offices, RSE, ASB

OPI: MPTS, Standards and Labeling Division

United States Department of Agriculture

Food Safety and Inspection Service

FEB 27 1986

To: Branch Chiefs, SLD

Policy Memo 066A

From: Margaret O'K. Glavin, Director
Standards and Labeling Division

Margaret O'K. Glavin

Subject: Red Meat Products Containing Added Solutions

ISSUE: The labeling of red meat products containing added solutions.

POLICY: This Policy Memo replaces 066 and the present entry in the Policy Book entitled "Water-Base Seasoning Solutions Allowed in Beef, Fresh or Cooked."

Solutions of any amount may be added to cured or uncured red meat products including those that have been chunked, ground, wafer sliced, etc., and formed, if the product name is qualified by a statement indicating the composition and the amount of the added solution. The statement must identify the common or usual names of all the ingredients added in their proper order of predominance and may identify the method of addition, e.g., injected, massaged, dipped, etc. An example of an acceptable qualifying statement is "Injected with up to 20 percent of a solution of water, salt, and sodium phosphates." Other similar statements will be considered on their merits. The statement must be contiguous to the product name and printed in a style and color as prominent as the product name. The statement must be at least one-fourth the size of the most prominent letter in the product name except the ingredients of the solution can be in print no less than one-eighth the size of the most prominent letter in the product name.

Since the regulations (9 CFR 319.101 & 102) allow uncooked corned beef brisket to contain 20 percent and uncooked corned beef round and other cuts 10 percent of a curing solution above the weight of the fresh uncured product, the above labeling scheme does not apply until these levels are exceeded. Similarly, the labeling scheme does not apply to uncooked cured pork trimmings or uncooked cured pork which is not labeled to indicate the presence of hams, loins,

shoulders, butts, picnics or cured pork made from parts not covered by the Protein Fat Free regulations, until more than 10 percent added substance is present. If uncured products to which solutions are added are subsequently cooked, a statement of the composition and the amount of the solution added prior to cooking must accompany the product name. The statement may include an indication that the addition took place prior to cooking, e.g., "Prior to cooking injected with up to 20 percent of a solution of water, salt, and sodium phosphates." A statement of the amount of solution remaining after cooking may also be included. This is determined by subtracting the weight of the fresh meat article from the weight of the finished product.

The labeling of cured, cooked products such as ham and corned beef is covered by other regulations and policies.

Except for the situations identified below, a partial quality control program for the addition of solutions must also be approved by the Processed Products Inspection Division before the label can be used regardless of the amount of solution added.

The addition of an enzyme solution to meat products is limited to 3 percent by regulation (9 CFR 318.7(c)(4)) and is not subject to a partial quality control program. If a product is treated with an enzyme solution and a flavoring solution, separately or in one step, both treatments should be separately identified on the label.

In situations where it has been customary to mix up to 3 percent water with seasonings and flavorings and rub the mixture onto the surface of the meat, the qualifying statement describing this treatment does not have to include the amount and a partial quality control program is not needed. If, however, the water is incorporated into the meat by extensive rubbing or by massaging or tumbling, a statement of the composition and the amount of any solution absorbed is needed as described herein. An approved partial quality control program is also needed.

For products marinated with a solution up to 10 percent, the qualifying statement does not have to include the percentage of solution contained in the product. The term "marinated" and similar terms may not be used if the amount of solution added to the product is above 10 percent. Moreover, if the amount of solution added is above 10 percent, the statement indicating the presence of the solution must identify the percentage of the solution, e.g., "Containing 15 percent of solution of water, salt, sugar, and sodium phosphates." Products marinated with solutions up to 10 percent are not

subject to a partial quality control program.

The policy is intended to apply to solutions that impart favorable flavor and other sensory characteristics, but not to solutions that contain ingredients used to extend a product such as isolated soy protein.

Processors of products with labeling not in compliance with this policy memo and/or in need of a partial quality control program must make the necessary labeling changes and/or acquire approval of the partial quality control program within 6 months of the date of this policy memo.

RATIONALE: The addition of various solutions has been approved in various products including beef for further cooking, roasts, and steaks. These solutions are added by various means to impart favorable flavoring and other sensory characteristics to the finished product. Existing policies and regulations, however, do not address the addition of solution to meat products, in all cases, and often place a limit of 10 percent on the addition in most situations. Additions above those now permitted are considered appropriate, but since the nature of the meat products is changed, it is necessary that the product be labeled to identify the amount and composition of the solution.

Both the meat and poultry regulations require that a product have a standardized name or if none exists a common or usual name. If neither exists, the product must have a truthful descriptive name. Because these products, which contain solutions, have neither a standardized nor a common or usual name, a descriptive name is needed. The traditional name, supplemented with the required qualifiers to create the necessary distinction from the traditional product, serves this function.

The need for a quality control program is consistent with our past labeling policies for use of percentage declarations on labeling. A quality control program is required in all cases since the amount of the solution that can be added will no longer be subject to any upper limit.

United States Department of Agriculture

Food Safety and Inspection Service

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To: Branch Chiefs
Standards and Labeling Division, MPITS

Policy Memo 095

From: Margaret O'K. Glavin, Director
Standards and Labeling Division, MPITS

Margaret O'K. Glavin

Subject: Colored Casings-Labeling of Meat and Poultry Products

Issue: What are the labeling requirements for meat and poultry products in colored casings that do not transfer color to the products?

Policy: Colored casings on meat and poultry products which do not transfer color to the product, but which change and give a false impression of the true color of the products, must be labeled to indicate the presence of the casings. Acceptable terminology includes "Casing Colored" or "Artificially Colored." These phrases must appear contiguous to the product name.

Casings which are the same color as the product or are not misleading or deceptive, e.g., a white opaque casing on a summer sausage, do not have to be so labeled. Also products consisting of whole muscle bundles, e.g., hams, pork butts, etc., packaged in colored wrappings where a cut surface is not visible through the casing are exempt from this labeling.

Rationale: Under the provisions of Sections 301.2(ii)(4) and 381.1(b)(30)(iv) of the Federal meat inspection regulations and the poultry products inspection regulations, respectively, a product is considered misbranded if its container (e.g., casing) is "made, formed, or filled as to be misleading." Section 317.2(j)(8) adds "...no such casing may be used if it is misleading or deceptive with respect to color, quality, or kind of product." Therefore, for many years colored casings that changed the expected or true color of the product could only be used if the product name was clearly and properly qualified to indicate the presence of the casings. Thus the consumer could make an informed

selection in the marketplace about the true nature of the product. The use of colored wrappings on whole muscle bundles is widespread apparently due to esthetic reasons. In this situation, the coloring should not mislead the consumer into believing that the product is leaner, different, or of a better quality than similar products. If a cut surface is visible, the potential for deception is a real possibility. Since there has been some confusion over the intent of this policy, this policy memo is being issued to reiterate the policy and clarify its intent.